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**The acceptability of collecting samples from
Understanding Society participants for microbiome
analysis**

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Non-technical Summary

The purpose of *Understanding Society* is to provide high quality longitudinal data on topics such as health, work, education, income, family and social life. In previous waves, nurses collected blood samples from participants, supporting research in the biosocial research arena. ISER are exploring the possibility of collecting further biological samples. This includes requesting a stool sample from participants for microbiome analysis, offering the potential to provide novel and useful biosocial insight.

ISER commissioned Kantar to conduct in-depth interviews with *Understanding Society* participants to explore views on the acceptability of requesting a stool sample and to gather feedback on prospective study materials. The study comprised 25 face-to-face in-home depth interviews that lasted approximately 45 minutes. Participants were recruited from the *Understanding Society* Pilot Sample following an opt-out exercise. Researchers used a semi-structured discussion guide and a range of stimulus materials during the discussions.

Participants' views on providing a stool sample fell along a spectrum of more to less acceptable, with three broad groups emerging – 'Willing', 'On the fence', and 'Not willing'. The three groups had similar and overlapping information needs, specifically an interest in the wider purpose of the study and more detail about collecting the sample.

Those 'On the fence' were less comfortable and more squeamish than the 'Willing', so designing the collection with them in mind will likely address the needs and concerns of both groups:

- Highlight the **purpose and wider benefits** of the study – while those 'On the fence' were less motivated by prosocial messages than the 'Willing', if combined with other reassurances it may help to nudge them towards acceptance
- Give participants '**enough**' **information** about the collection up front (e.g. the Participant Information Sheet content), so they can make an informed decision as early as possible and avoid them dropping out later in the process
- Provide a **channel where participants can find further information** or ask questions, for example a website or a helpline
- Allow some **flexibility in collection procedures**, if possible by giving them a choice of collection kit, providing additional materials, or arranging a courier to collect the sample if that is preferred to sending by post.

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Participants' views on providing a stool sample fell along a spectrum of more to less acceptable, with three broad groups emerging – 'Willing', 'On the fence', and 'Not willing'. The three groups had similar and overlapping information needs, specifically an interest in the wider purpose of the study and more detail about collecting the sample.

Keywords: qualitative, biomeasures, microbiome

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Executive Summary

Understanding Society is a longitudinal study that follows the lives of individuals in 40,000 households in England, Scotland, Wales and Northern Ireland, led by the Institute for Social and Economic Research (ISER) at the University of Essex. Its purpose is to provide high quality longitudinal data on topics such as health, work, education, income, family and social life. In previous waves, nurses collected blood samples from participants, supporting research in the biosocial research arena. ISER are exploring the possibility of collecting further biological samples. This includes requesting a stool sample from participants for microbiome analysis, offering the potential to provide novel and useful biosocial insight.

ISER commissioned Kantar to conduct in-depth interviews with *Understanding Society* participants to:

- **explore views on the acceptability of requesting a stool sample** – to ensure it would not result in participant drop-outs and reduced uptake in future sample / data collection waves
- **gather feedback on prospective study materials** – to ensure they are participant-friendly and all information provided is clear and concise, so that participants can make an informed decision. This included asking participants to review commercially available stool collection kits.

The study comprised 25 face-to-face in-home depth interviews that lasted approximately 45 minutes. Participants were recruited from the *Understanding Society* Pilot Sample following an opt-out exercise. The sample was weighted towards younger respondents and sought a gender balance. Researchers used a semi-structured discussion guide and a range of stimulus materials during the discussions. Participants reviewed prospective study materials and a range of stool collection kits and were asked for feedback. Findings from this study will be used by the research and study design teams at ISER to inform the design of study materials and protocols.

Acceptability of providing a stool sample

Participants' views on providing a stool sample fell along a spectrum of more to less acceptable, with three broad groups emerging – 'Willing', 'On the fence', and 'Not willing'. The three groups had similar and overlapping information needs, specifically an interest in the wider purpose of the study and more detail about collecting the sample. Preferences were more polarised in relation to sample collection and kits, driven by how comfortable participants felt with the idea of providing a stool sample.

'Willing' participants tended to be older (aged 35+) and often had been involved with *Understanding Society* for longer than those who were less willing. They commonly spoke positively about their participation in *Understanding Society* and were driven by a sense of commitment to taking part in the survey each year. Those 'Willing' believed that providing a stool sample would have wider societal benefits, but wanted more detail about the expected benefits or outcomes from the study, as well as details about sample collection.

Participants that were 'On the fence' shared motivations and questions in common with the 'Willing' group but wanted more information about the study before deciding to take part. Those 'On the fence' tended to be younger (aged 18-34) and their involvement with *Understanding Society* was shorter and more sporadic. They tended to expect an incentive in return for providing a stool sample. Due to heightened concerns about providing a stool sample, this group wanted more detail about how collecting the sample would work in practice. They responded positively to reassurances that the process would be straightforward and discreet.

Only two participants said they were 'not willing' to provide a stool sample, however due to sample size and the qualitative nature of study it is not possible to generalise this proportion. Their main concerns were primarily discomfort with collecting and storing the sample. Though they were unsure or unwilling to take part, like the 'Willing' and 'On the fence' groups, they felt the benefits of the study could be clearer to encourage others.

In terms of developing study materials and designing collection procedures, it would be prudent to focus attention on those that are 'On the fence'. 'Willing' participants were already motivated by their experience with *Understanding Society* and a sense of contributing to the greater good, so they would be likely to participate regardless of the information provided or the collection procedures. The research also suggests there are some people for whom little could be done to encourage them to provide a stool sample. Those 'On the fence' needed more information and reassurances about collecting the sample, so to encourage participation their information needs and concerns should be prioritised.

Information needs

Participants felt the informational materials (Advance Letters and Participant Information Sheet - see Appendix E-G) could be more specific about what the potential benefits might be and felt this would encourage participation. Participants responded positively to the Participant Information Sheet (Appendix G) and felt it provided the desired details about how the sample would be collected in a reassuring tone. Overall, participants felt that it would be sensible to provide the Participant Information Sheet alongside a shorter Advance Letter that concisely sets out the most pertinent information – namely the request, project aims, potential wider benefits, what is required and next steps – and signposts to further information.

Preferences for collecting sample

Participants found the Collection Protocol (Appendix I) difficult to follow and strongly preferred the visual instructions and diagrams that were included in the commercial kits. Any written instructions about collecting the sample should be simple, but detailed, and go step by step so it leaves no doubt what participants should do. Supplementing written instructions with diagrams or images may further reduce uncertainty.

Those that were 'On the fence' or 'Not willing' were squeamish about collecting a stool sample and preferred Kit 1 (Appendix J) as it looked easier to use and more robust, and it didn't require them to 'handle' the sample (i.e. scooping). Given the strength of concerns about collecting the sample, if going forward with Kit 4 (Appendix J), it's important to take practical steps that will reassure participants; for example, giving more than one paper collection device as a back up.

Participants were concerned about storing the sample in the freezer, and while it was a deal breaker for some 'On the fence', it did not discourage 'Willing' participants. While those 'On the fence' preferred Kit 1 for its ease of use, all things being equal, they would prefer not to store the sample in the freezer, so choosing Kit 4 might encourage some to take part. Those 'On the fence' preferred the sample be collected by a courier or nurse because it provided reassurances it would be handled sensitively, while those that were 'Willing' expected returning the sample by post would be easier and more convenient. To persuade those 'On the fence' who may feel uncertain, it's important to stress that the sample will be returned securely by post and emphasise the relative convenience of being able to return the sample when it suits them.

Key Recommendations

Those 'On the fence' were less comfortable and more squeamish than the 'Willing', so designing with them in mind will likely address the needs and concerns of both groups:

- Highlight the **purpose and wider benefits** of the study – while those 'On the fence' were less motivated by prosocial messages than the 'Willing', if combined with other reassurances it may help to nudge them towards acceptance

- Give participants '**enough**' **information** about the collection up front (e.g. the Participant Information Sheet content), so they can make an informed decision as early as possible and avoid them dropping out later in the process
- Provide a **channel where participants can find further information** or ask questions, for example a website or a helpline
- Allow some **flexibility in collection procedures**, if possible by giving them a choice of collection kit, providing additional materials, or arranging a courier to collect the sample if that is preferred to sending by post.

1. Introduction

1.1 Background

Understanding Society is a longitudinal study that follows the lives of individuals within 40,000 households in England, Scotland, Wales and Northern Ireland. It is an internationally recognised study led by the Institute for Social and Economic Research (ISER) at the University of Essex, and it is the largest study of its kind in the world. The overall purpose of *Understanding Society* is to provide high quality longitudinal data on topics such as health, work, education, income, family and social life. It provides vital evidence for scientists and policymakers on the causes and consequences of deep-rooted social problems.

Nurses collected blood samples from *Understanding Society* participants in waves 2 and 3 (2010-2012) of the study, which has enabled many genetic and biomarker publications and will support continued research in the biosocial research arena. ISER would like to collect a wider range of biological samples in future waves of the study. The collection of stool samples from the general population for microbiome analysis has the potential to provide novel and useful biosocial insight.

1.2 Aims

ISER are interested in requesting a stool sample from *Understanding Society* participants as an additional biological sample for the study. This research sought to assess the feasibility of including a stool sample and gather participants' views on the acceptability of such a request. In the UK, older people¹ may have been invited to provide a stool sample as part of the national bowel cancer screening programme, but it is unclear how acceptable the collection of a stool sample would be to *Understanding Society* participants, particularly participants between the ages of 20-50 years.

This research study had two main aims:

- **Gather participants' feedback on acceptability of providing a stool sample:** This research sought to gather participants' views and feedback on providing a stool sample for microbiome analysis. This is of importance to the *Understanding Society* longitudinal study to ensure that including a request to collect a stool sample from participants would not result in participant drop-outs and reduced uptake in future sample / data collection waves.
- **Gather feedback on prospective study materials and collection kits:** This research also sought participant feedback on prospective documents and materials that may be used for the study to ensure they are participant-friendly and all information provided is clear and concise, so that participants can make an informed decision. This research study also involved asking participants to review commercially available stool collection kits and give feedback.

¹ Aged between 60 and 75 years in England, Wales and NI, and from 50 in Scotland

This research was a small scale pilot study to determine the feasibility of the methods proposed for fieldwork with the wider Health Innovation Panel² and main *Understanding Society* study. Findings from the study will be used by the research and study design teams to inform the design of study materials and protocols.

1.3 Methodology

This research comprised 25 face-to-face qualitative interviews. For more information about the sampling and recruitment process, see Appendix 1. Due to the sensitive nature of the topic being discussed, interviews were conducted face-to-face in participants' homes where they would be more comfortable providing feedback. Interviews lasted approximately 45 minutes and participants received £40 token of appreciation in recognition of their time and to encourage participation. Participants were briefed by the interviewers on the purpose of the study and received a consent form to sign in advance of the interview taking place. Fieldwork took place in January 2019.

Interviewers used a semi-structured discussion guide (see Appendix D) and a range of stimulus materials (Appendix E-J) during the discussions. Participants reviewed prospective study materials and a range of commercially available stool collection kits and were asked for feedback.

The sample was weighted towards younger respondents and sought a gender balance. An overview of the qualitative sample can be found below:

| | |
|--------------------------|----|
| TOTAL | |
| 25 DEPTHS | 25 |
| PRIMARY QUOTAS | |
| LOCATION | |
| London | 11 |
| South East | 2 |
| South West | 4 |
| West Midlands | 1 |
| East Midlands | 3 |
| Yorkshire and the Humber | 3 |
| North West | 1 |
| MALES AGED | |
| Males 18-24 | 3 |
| Males 25-34 | 3 |
| Males 35-44 | 2 |
| Males 45-54 | 1 |
| Males 55+ | 4 |
| FEMALES AGED | |
| Females 18-24 | 1 |
| Females 25-34 | 3 |
| Females 35-44 | 2 |
| Females 45-54 | 3 |
| Females 55+ | 3 |

² The Innovation Panel includes experiments and methodological tests (in a context similar to the main *Understanding Society* survey) designed to develop and evaluate methodologies and new content for longitudinal survey research.

The sample for this study was drawn from *Understanding Society* Pilot Sample, which has been used to pilot fieldwork procedures and questionnaires before the main sample is issued.

1.4 Reading this report

This report draws on findings from qualitative research. Due to the flexible and open nature of qualitative methods, this research does not seek to quantify or be generalisable to the overall population but reflects a range of attitudes and preferences of the participants we spoke to.

Throughout the report, verbatim quotes are used to illustrate findings. To provide additional detail, quotes are labelled with gender, age, and location. For example: “*Quote.*” (Male aged 25-34, London)

2. Acceptability of providing a stool sample

Participants' views about providing a stool sample fell along a spectrum of more to less acceptable. Although not discrete categories, participants generally fell into one of three groups according to whether or not they would be willing to provide a stool sample: 'willing', 'on the fence', and 'not willing'. In this section, we discuss each of the three 'groups' in turn.

These groups tended to have overlapping motivations driving whether they would be willing to provide a stool sample, and shared some concerns and information needs in common. Most participants in our sample reported that they would agree in principle to provide a stool sample for microbiome analysis. However, the small-scale, qualitative nature of this study means it is not possible to generalise from these findings to the wider *Understanding Society* participant population.³

Participants were asked whether they would be likely to provide a stool sample at two points: after reviewing the advance letter (see Appendix E and F) and again near the end of the discussion, after having reviewed all informational materials and the sample collection kits. Participants were 'assigned' to one of the three groups on the basis of the answer they gave at the end of the discussion.

2.1 'Willing' to provide a stool sample

As noted above, most participants in our sample reported that they were likely to agree to take part and provide a stool sample by the end of the discussion. These participants were evenly split between men and women but skewed towards older participants (all were 35+). Several of these participants also had previous experience of providing a stool sample and acknowledged that this made them more comfortable with the idea.

The 'willing' participants spoke positively about their participation in the *Understanding Society* study and this was a motivation for agreeing to provide a stool sample. Many had been participating in *Understanding Society* for many years, and so there was a sense of continuity and routine driving their agreement.

"[Understanding Society] has become part of the annual routine" (Male aged 55+, London)

"It would feel weird if we didn't do it one year" (Male aged 35-44, London)

"I have developed a little bit of loyalty [to the study]." (Male aged 55+, London)

'Willing' participants also seemed to understand the need to collect population data and the wider benefits to government and society. This sense of contributing to the 'greater good' also influenced participants' willingness to take part.

"The government need access to important data and what you see in the headlines shapes that."
(Male Aged 45-54, South West)

"I understand the benefit of long-term data. It's very important." (Male aged 55+, London)

³ There is also a risk that those who initially agreed to take part in these discussions are already more comfortable with the topic and thus more likely to say they would participate than those who were not willing to take part in this research.

"I'd agree [to provide a stool sample]. It's helping, helping to combat disease in the future. The money is nice, but not the reason why now. And it's not such a big deal to go to the loo!" (Male aged 35-44, East Midlands)

'Willing' participants also found it motivating that the microbiome study would contribute to health research. This was often driven by a personal connection; for example, a loved one with a health issue.

"I definitely would [provide a stool sample], my husband would and my daughter too as we all suffer with IBS type problems and it may help us understand why." (Female aged 55+, North West)

Despite this broad support, 'willing' participants still had some concerns. In particular, they queried why they were receiving the invitation and whether they were being targeted in some way; for example, because they were older.

"Would older people feel, 'oh is it because I'm getting old?'" (Female aged 55+, London)

Participants (both 'willing' and 'on the fence') wanted clarity on whether they would receive any individual results from their sample. While this was not spontaneously raised as an issue by participants, they were prompted once it was mentioned in Advance Letter 2 (see Appendix F),

"They need to make that clearer, that you'll not get any results whatsoever." (Male aged 35-44, East Midlands)

Because this group were willing to provide a stool sample and motivated by a sense of contributing to the greater good they wanted more information about the wider purpose and benefits of the study; for example, what *Understanding Society* expect to learn from it and how it will benefit society. This was still a lingering question by the end of the discussion and participants wanted to know more.

"I'd be intrigued why they are asking to provide a sample and ascertain the life style aspects of analysing the sample." (Female aged 25-34, South West)

Finally, because this group was willing to take part, they were keen to have more detail on logistics of collection and how it will work in practice.

2.2 'On the fence'

A smaller number of participants could be described as being 'on the fence' as to whether they would agree to participate and provide a stool sample. This group shared motivations and concerns in common with the 'willing' group but generally wanted more information about the study after reviewing the advance letters, particularly about collecting the sample. Once they'd been presented with all the informational materials and collection kits, they still felt unsure about whether they would take part or their participation was contingent on a certain condition; for example, not having to store the sample in the freezer (see Section 4.3 on storage of sample).

This group was also evenly split between male and female but was skewed toward younger participants (all were between 18-34). Many in this group first became involved with *Understanding Society* as children because their parents participated in the study. They had varying levels of current involvement with *Understanding Society*, and so they appeared to be less 'loyal' than older participants who had been participating in the study for many years.

This group was less motivated by a sense of 'greater good' and tended to expect something in return for their participation. Some participants queried whether there was a financial incentive for taking part. Others wondered whether they would receive individual health results as they did not completely understand that they would not receive results.

"What will you get for doing it, how much money? I got £20 for the questionnaire last time, so maybe £50 for this? Maybe less, it depends how poor I am at the time and if I have a [football] match to travel to as it's expensive." (Male aged 18-24, Yorkshire and the Humber)

"For me, I would actually want the diagnostic tests because it gives me more information about my health." (Female aged 18-24, London)

This group's uncertainty about providing a stool sample prompted concerns about the opt-out exercise. To a few participants it seemed wrong that if no contact it was assumed you would be willing to take part. Like the 'willing' group they were interested in how providing the sample would work in practice, but for them, their participation was more conditional on whether they were happy with the way the sample would ultimately be collected, stored and returned. In some cases, those that were more willing at the start of the interview changed their minds when additional detail about collecting the sample was provided and they were confronted with having to handle the sample. However, this group seemed more willing to take part where there were reassurances that the process would be simple and straightforward.

Like the 'willing' group, participants that were 'on the fence' wanted more information about the purpose of the study and felt this would motivate participation.

"Education about it for me is important. I want to know why I am doing something and what for." (Female aged 25-34, London)

"I think that would grab people's attention, especially if they know someone who has been affected by anything that is being looked into." (Female aged 25-34, London)

In general, this group had an appetite for more and detailed information about the study, which would address their concerns (or not) and help them to decide whether they would participate.

"I think because it is something that is quite personal I prefer as much information as possible." (Female aged 25-34, South West)

2.3 'Not willing' to provide a stool sample

There were only two participants interviewed who said they were not willing to provide a stool sample. Though due the small sample size and qualitative nature of this study, it's not possible to generalise this proportion to the wider population. In addition, as discussed before, those that were willing to take part in a discussion about providing a stool sample may be self-selecting to a degree, and thus more likely to be willing to provide a stool sample.

Both of the 'not willing' participants were Muslim women. One participant was younger (age 18-24) and had only been participating in *Understanding Society* for a couple of years. She was not willing to take part, primarily due to embarrassment and discomfort with collecting and storing the sample. For her, storing the sample in the freezer was a deal-breaker.

She also felt the purpose and wider benefits of taking part in the study were not sufficiently clear.

"They could explain better that they need samples from lots of people to understand what's going on in the bowel and what factors affects it and it's going to help people generally in the future." (Female aged 18-24, North West)

The other participant was older (age 35-44) and had also been participating in *Understanding Society* for a few years. Her English was limited so she struggled with the materials and understanding the information provided. She was very unsure and gave the impression she was uncomfortable with providing a sample. She said she would need to discuss it with her husband and may require some assistance to go through the instructions.

3. Responses to informational materials

In this section we report on participants' views and feedback on the prospective study materials and explore how this varies depending on participants' willingness to take part. In the conversations with participants (detailed in Discussion Guide in Appendix D), they were first shown an advance letter, followed by the participant information sheet, and consent form.

3.1 Advance letter

Participants were presented with two different versions of an advance letter (see Appendix E and F), with one letter longer and more detailed. Participants were shown both letters and then asked to compare them, exploring their preferences. The order in which these letters were presented to participants was rotated to ensure there was no order bias.

Participants felt the shorter letter was succinct and to the point, but missed key information about the study, notably the overall purpose of the study and how they expected the results would be used. It was clear samples would undergo microbiome analysis, but participants wanted to know what the wider benefits or impacts might be. Participants also wanted to know how providing the sample would work in practice, particularly those that were 'on the fence', in order to make a decision.

"I wouldn't mind a bit more of why they're doing it and what they're trying to gain from it." (Male aged 35-44, London)

Participants appreciated that the longer letter gave a bit of insight as to what the process would be like and provided reassurances. Participants generally had fewer questions about the study after reading the longer letter, and, where they read the longer letter second, they felt some of their questions or concerns had been addressed. However, participants felt that at points, the longer letter was too technical. In particular, some felt that the information under 'Why is the study being done' was too complex and less directly relevant to them. They also felt it didn't speak to the broader benefits of doing the study, which is what the subheading would suggest.

"I feel that overall it's very clear and quite reassuring. It tells you a rough idea of what it is, how long it will take. It's quite a scary thing but the way it is phrased makes you feel that it is harmless." (Female age 25-34, South West)

"It's filled you in on what you would require of people and the reason why." (Female aged 55+, London)

Given a choice between both letters, participants tended to prefer the longer letter because it gave more detail about the purpose of the study and how it would work in practice, which 'willing' and 'on the fence' groups wanted. However, when participants were later presented with the participant information sheet (see Section 3.2), they felt that this could accompany a shorter letter like Advance Letter 1.

3.2 Participant information sheet

Following reviewing the advance letters, participants were shown the participant information sheet (see Appendix G). Overall, participants responded positively to the participant information sheet, specifically how it was designed, the information it contained, and the tone. Participants mostly found the images and colour

appealing and engaging, however a few felt it was 'less professional and medical' or 'childlike'. In particular, participants liked the way information was divided amongst different headings and visually presented.

"The visuals and small blocks of text make it much better, much easier to understand and absorb."
(Female aged 35-44, West Midlands)

"I think it looks brilliant. About the right length. Nice and readable." (Male aged 55+, London)

Participants appreciated the additional detail on how the sample would be collected, and the information sheet made it seem simple and discreet; for example, 'collecting your stool sample should take just a few minutes'. However, some participants, particularly those that were willing, wanted additional detail about collecting the sample:

"It still doesn't explain how you do the sample...there's got to be some scooping involved somewhere." (Female aged 45-54, London)

Participants still wanted more clarity on the purpose of the study and what the potential benefits might be; for example, improved understanding of diseases. This was seen as a motivation to take part, particularly where participants had a personal connection to one of the diseases listed. For example, one participant had diabetes:

"When I see it affects me, the more likely I am to be accepting." (Male aged 25-34, London)

The information under 'Can I receive results from my sample' was not fully understood by all participants. In particular, phrases like 'clinical diagnostic tests' and 'directly clinically relevant incidental findings' were challenging. Participants also questioned the use of 'we do not expect to find', which left open the possibility that they might find something.

As discussed in Section 3.1, most participants expected to receive the participant information sheet along with a shorter letter.

"Would be nice to see this first. Is there any reason why you couldn't receive it with the letter?" (Male aged 55+, London)

While participants were generally happy with the level of information provided in the participant information sheet, some felt others would have more specific questions and there should be a place to get even more information.

"Even with this you might have more questions. You could do some more research online. You want it to be as hassle free as possible, so if you are interested, the information is there, you don't have to ask for it. If you are on the fence, it might be something that tips you over either way. If you are not interested, there is no harm done." (Female aged 25-34, London)

3.3 Consent form

After reviewing the participant information sheet, participants were given the consent form (see Appendix H). Participants did not express strong views on the consent form and felt it was 'pretty standard' and much like other consent forms they've seen before. However, the consent form did contain new information that participants raised concerns about. Some participants felt the 'future research' line (line #6) was vague and wanted more specificity or a finite amount of time that the sample would be stored.

"I still have my worries. I don't really know what they are going to do, or what they can do." (Male aged 18-24, London)

This concern was driven by a fear that in the future, their stool sample could be used in a way not specified (that the participant would not be able to anticipate or conceptualise), which they also have not explicitly consented to. However, not all participants were concerned about storage and future research.

"Once it leaves this house it is theirs. I'm not going to go for custody or anything, they can do what they want with it." (Female aged 45-54, London)

Participants also raised concerns about having more than one statement per box (for example lines #2 and #7) and felt they should be separated so they can provide consent (or not) to individual statements. Finally, a few participants struggled with the language here; for example 'satisfactorily', 'anonymised,' and 'statistical.'

3.4 Recommendations

Participants were most positive about the participant information sheet and felt it was engaging, and answered their questions and addressed most of their concerns. As such, it would be sensible to provide this (with a few changes discussed in Section 3.3) alongside a shorter advance letter that succinctly sets out the most pertinent information.

The advance letters should aim to cover:

- **The request** e.g. *We would like to invite you to participate in the Understanding Society Microbiome Pilot Study*
- **Aims of the project** e.g. *This is a new project we are undertaking to better understand the different types of bacteria that live in the bowels of different people*
- **Potential wider benefits or expected outcomes** e.g. *This would help improve our understanding of diseases and/or help us to understand the influence our lifestyles and environments have on our health*
- **What they will have to do** e.g. *We would ask you to provide us with a stool sample and complete a short questionnaire about your general health, lifestyle and dietary habits*
- **Place where they can get more information** e.g. referencing the participant information sheet or providing a website address or contact details
- **Next steps** e.g. *If you're willing to take part, you do not need to reply to this letter. We will follow up to confirm that you've agreed to participate.* As well as instructions for how to opt out.

Throughout, it's important to be mindful of the language and terminology used, avoiding technical language and using plain English wherever possible. Technical language like '*clinical diagnostic*' and '*informed consent*' were not necessarily understood by all participants, and they could be defined or replaced with plainer language; for example, '*we need your permission*' rather than '*informed consent*'.

4. Preferences for collecting sample

After reviewing the informational materials about the Microbiome Pilot Study, participants reviewed the Collection Protocol (see Appendix I) and commercially available sample collection kits (see Appendix J). Participants' preferences for collecting, storing, and returning a stool sample were varied, reflecting individual preferences. But there were some common concerns and preferences amongst the different groups, which are detailed below.

4.1 Collection protocol

Participants were asked to review the collection protocol alongside Kit 2 (see Appendix J), as it most closely aligned to the protocol instructions. Participants typically found the Collection Protocol difficult to follow as the instructions in the protocol did not directly align with any of the kits reviewed, so participants had a more challenging task of imagining the kit the protocol described. Participants said they would have preferred something with diagrams or pictures, as they felt it would be clearer what they should do.

"Anyone can look at a diagram and understand. I automatically look at the pictures before I look at the words." (Female aged 25-34, South West)

Participants also felt the directions could be clearer and should present instructions in a chronological order. For example, under the *'Before Collecting Your Sample'* header, the protocol gives instructions on how to dispose of materials when finished and instructs them to wash their hands, which felt jarring under that heading.

4.2 Kit preferences

After being shown the collection protocol and Kit 2, participants were shown the remaining three stool collection kits (see Appendix J). The order the kits were shown was rotated to ensure the order did not impact on participants' preferences. Those that were 'on the fence' or 'not willing' to take part preferred Kit 1, which was the kit for collecting a full stool sample. For these participants, it looked easier to use and more robust than the paper collection devices. Participants also liked that this kit did not require them to 'handle' the sample (i.e. scooping) which seemed more hygienic.

"Seems easier. It is clear how it needs to be used and is collected all in one place." (Female aged 18-24, London)

"Wide enough and large enough to collect the sample. Less handling for me." (Male aged 25-34, London)

Heightened concerns about collection and handling the sample suggests that 'on the fence' participants were more squeamish than 'willing' participants. In particular, 'on the fence' participants were concerned about kits with paper collection devices, as they seemed more likely to fail or fall apart, making the process messier and more difficult.

"I'd want something bigger and stronger." (Male aged 18-24, Yorkshire and the Humber)

However, for Kit 1 (as well as Kit 2 and Kit 3), the sample would need to be stored in the freezer, which was not appealing (see Section 4.3 for more detail).

'Willing' participants' preferences weren't as pronounced as those 'on the fence'. Some preferred Kit 1 for the same reasons as those that were 'on the fence', namely ease of use. However, 'willing' participants found Kit 4 appealing because you didn't have to store it in the freezer and the sample could be dropped in the post.

"Most people aren't at home when their post comes so having something that fits through the letterbox is important and you don't have to put it in the freezer." (Female aged 25-34, South West)

"Definite plus. I wouldn't particularly want to put a biological sample in the freezer." (Male aged 55+, London)

This suggests 'willing' participants were more focussed than other groups on the practicalities of collecting the sample through to returning it.

4.3 Storage of the sample

As previously discussed, participants were concerned about storing a stool sample in their freezer, and, for this reason, that Kit 4 did not have to be stored in the freezer was seen as great advantage. In some cases, this caused participants to change their preference, favouring Kit 4 over Kit 1.

For 'willing' participants, storage of the sample was not a deal breaker, and while they did not love the idea of storing a stool sample in the freezer, it wouldn't discourage them from taking part.

"For me, putting it in the freezer wouldn't be the method I choose just because it would be with perishable foods. But obviously it would be in a sterile container...that wouldn't put me off." (Female Aged 25-34, South West)

"I can see a lot of people thinking it wouldn't be particularly appealing but if it is all sealed away then that wouldn't be a huge issue for me." (Male aged 25-34, South West)

For participants that were 'on the fence', their concerns about collecting the sample (i.e. ease of use) were prioritised over their concerns about storing the sample in the freezer. Although these participants were uncomfortable with storing the sample in their freezer, it did not change their preference for Kit 1.

Participants were also concerned about how long the sample would have to be kept in the freezer, and they preferred it to be collected as soon as possible. For most, within a week seemed reasonable.

"I wouldn't want it to be in the freezer for long. I'd want it picked up in a few days...a week at the very most." (Female aged 55+, North West)

4.4 Returning the sample

Preferences on returning the sample tended to be connected to participants' kit preferences. Those that preferred partial (smaller) sample kits were more likely to prefer returning the sample by post, while those that preferred the full (larger) sample tended to prefer the sample be collected by a courier or nurse. In addition, participants that were 'on the fence' expressed a preference for having a courier or nurse collect their sample, as it provided reassurance that it was being professionally handled.

"If it is with a nurse, it is with a professional. I have to be confident where it is and where it is going. If I'm not, I would rather not take part." (Male aged 25-34, London)

Although 'willing' participants in some cases preferred a courier or a nurse to collect the sample for the same reasons, they were more open to returning the sample by post, expecting that it would be easier and more convenient.

"I wouldn't have to wait in for anyone." (Female aged 55+, London)

4.5 Recommendations

As discussed in Section 4.1, the generic collection protocol did not match up directly with any of the kits, which caused confusion, so any instructions should be thoroughly tested for understanding so it leaves no doubt what participants are meant to do. Participants also strongly preferred visual instructions and diagrams, which would further reduce uncertainty.

Most participants felt anxious that they might mess up the sample collection, and there are practical things that could be done to put them at ease. If, for example, a kit with a paper collection device is ultimately selected, it would be prudent to give participants more than one collection device so they feel reassured they have a back up in case they mess up. If the kit that is selected has to be stored in the freezer, make sure to provide sterilisation wipes and opaque plastic bags to put the sample in before going into the freezer. Also, set up the collection so participants would not have to store the sample in the freezer for more than a week.

Given the lack of consensus around kit preferences, it will be difficult to please everyone. Those that were 'on the fence' were primarily concerned about collection device, so it may be prudent to give them the option to use Kit 1 even if that is not the kit that is ultimately chosen. To provide further reassurance, if feasible, give participants the option to have a courier collect their sample if preferred.

5. Conclusions

Participants had similar and overlapping information needs, specifically an interest in wider purposes behind the study and more detail about collecting the sample. Their preferences were more polarised when looking at sample collection and kit preferences, driven by how comfortable participants felt with the idea of providing a stool sample.

The 'willing' group's participation was not contingent on certain conditions, as they were largely motivated by their history and experience with the *Understanding Society* study and by a sense that they were contributing to the greater good. As a result, they would be likely to participate regardless of the information provided or the collection procedures or kit chosen.

On the other hand, those that were 'on the fence' needed more information before making a decision. In particular, they wanted to know more about how collecting the sample would work in practice. To encourage participation, this group's information needs and concerns should be prioritised.

Our research suggests there are some people for whom little could be done to encourage them to provide a stool sample. Further research is needed to establish the scale and characteristics of this 'unwilling' group.

As such, in terms of developing study materials and designing the collection procedures, it would be prudent to focus attention on those that are 'on the fence'. Although the 'on the fence' group is less comfortable and more squeamish than the 'willing' group, designing with them in mind will still likely address the needs and concerns of both groups.

Some key recommendations from our research:

- Highlight the **purpose and wider benefits** of the study – while those that were 'on the fence' felt unsure, they were motivated by the idea that providing a stool sample would contribute something to society
- Give them '**enough**' **information** about the collection up front (e.g. what's in the Participant Information Sheet), so they can make an informed decision and you can avoid them dropping out later in the process
- Provide a **channel where they can find further information** or ask questions, for example a website or a helpline
- Allow some **flexibility in collection procedures**, if possible by giving them a choice of collection kit or arranging a courier to collect the sample if that is preferred to sending by post.

Appendix A – Research Methodology

Sampling

Participants were recruited from *Understanding Society's* Innovation Panel sample, of which there were 854 original pieces of sample. Exclusions were applied (see below) before arriving at the 267 participants who were sent the opt out letter (see Appendix B).

Total number of participants in sample for the pilot study: 854

413 (INCLUDE only those last active in wave 9)

408 (EXCLUDE those with a recent code exclusion)

407 (EXCLUDE those with no DOB as can't calculate age for filter)

407 (EXCLUDE those with unknown address)

328 (EXCLUDE those aged < 18)

285 (INCLUDE those from regions in England for grouping)

267 of these have phone numbers to use for recruitment.

Recruitment

After excluding those with an unknown address or phone number and those under age 18, there were 267 eligible participants in this sample.

Kantar Public then posted an opt out letter (see Appendix B) to all 267 individuals detailing the microbiome pilot study and providing a Kantar Public Freephone number for them to call if they had any questions or would like to opt out from the recruitment process. During the two week opt-out period, 16 sample members were removed from the sample (a few of these were because the sample member had died). Following the two week opt-out period, sample members were purposively selected based on geographic clustering and socio-demographic factors. Sample members were contacted by the field recruitment team to invite them to participate in the study and 88 had been contacted to take part in the research before the target of 25 interviews was reached. This contact provided further information (see Appendix C) and involved agreeing a convenient date and time for an interviewer to visit the participant's homes. The strike rate is good (more than 1 in 4 agreed), but we cannot say much about why those that were contacted did not agree take part, as the recruiter does not typically record the reason. It may be that they simply weren't available when we were conducting interviews or that they couldn't be reached after a couple phone calls.

A final achieved sample table is below:

| | |
|-----------------------|----|
| TOTAL | |
| 25 DEPTHS | 25 |
| PRIMARY QUOTAS | |
| LOCATION | |
| London | 11 |

| | |
|----------------------------------|----|
| South East | 2 |
| South West | 4 |
| West Midlands | 1 |
| East Midlands | 3 |
| Yorkshire and the Humber | 3 |
| North West | 1 |
| MALES AGED | |
| Males 18-24 | 3 |
| Males 25-34 | 3 |
| Males 35-44 | 2 |
| Males 45-54 | 1 |
| Males 55+ | 4 |
| FEMALES AGED | |
| Females 18-24 | 1 |
| Females 25-34 | 3 |
| Females 35-44 | 2 |
| Females 45-54 | 3 |
| Females 55+ | 3 |
| SECONDARY QUOTAS | |
| ETHNICITY | |
| White - British | 18 |
| Black or Black British | 5 |
| Asian or Asian British | 2 |
| Socioeconomic Grade (SEG) | |
| AB | 7 |
| C2C2 | 10 |
| DE | 8 |

Analysis

Analysis drew on data from digital recordings, interview notes, transcripts, and researcher debriefs. Our approach to analysis includes the following stages:

- **Process-driven element** using our matrix mapping framework technique, as part of which data is coded and systematically summarised into an analytical framework organised by issue and theme. The framework is developed to reflect the research objectives and according to the themes emerging from the initial debrief session and data coding. The completed excel framework allows us to easily review and sort the data by theme, by case and across groups of participants ensuring a thorough review of the data.
- **Interpretative element** focuses on identifying features and patterns within the data, mapping the range and nature of data, finding associations, defining concepts, creating typologies, undertaking sub-group analysis. This process creates descriptive accounts and explanatory data, which comes not only from aggregating patterns but by weighing up the salience and dynamics of issues, and searching for structures within the data that have explanatory power. Researcher analysis sessions are used to support interpretation of the data, during which the team comes together to discuss and test emerging themes and insights.

Appendix B – Opt Out Letter

Dear [full_name],

Thank you very much for taking part in *Understanding Society*. Your participation continues to be very important to us.

I am writing to ask for your help on a linked research study which is being conducted by colleagues here at the Institute for Social and Economic Research (ISER), University of Essex in collaboration with Kantar Public.

The research team, led by Professor Meena Kumari, is doing some research on the collection of biomeasures (which can include blood, tissue and stool samples) which will help researchers understand influences on health and disease.

We would like to invite you to take part in a short interview in your own home for this study about your thoughts on what factors may promote and prevent a successful collection of biological samples. For the purpose of this interview we will be focussing on the collection of stool samples. This will be a different kind of interview, and will be more like a conversation to discuss your thoughts and views. Please note that we will NOT ask you to provide any biological samples as part of your participation in this project.

The interviews for this study are being undertaken by our fieldwork partners **Kantar Public**.

If you're willing to be contacted by Kantar Public then you do not need to reply to this letter.

After two weeks a Kantar Public researcher will contact you by email or phone to give you more information about this research, and if you are willing to take part, they will organise a time and place for the interview that suits you. The interview would take approximately 45 minutes. Participation is entirely voluntary.

Please be assured that information given as part of this study will be treated as confidential and will only be used anonymously for research purposes.

- In line with the Data Protection Act, Kantar Public will not link your name with any information you give and will hold your contact details securely at all times.
- Researchers will not be able to link the responses given with a specific person. Therefore no information you give will be linked to your previous or future survey responses.
- Kantar Public's overall findings will be published in a report to ISER, but it will not identify any individuals that took part in the research.
- You will receive a payment of £40 as a thank you for taking part. This could be a giftcard or PayPal transfer depending on your preference.

If you don't want Kantar Public to contact you, please let us know by 4th January 2019 by calling this Freephone number [freephone number] or emailing [Kantar Public contact] at Kantar Public at [email address]. You can also call this number if you have any queries about this request.

If you have any queries about your usual *Understanding Society* interview, or would like to let us know about a change in your contact details, please call our Participant Helpline.

Your participation in this study is entirely voluntary, but I really do hope you will be willing to take part as your views and opinions are very important to us.

Many thanks,

[Michaela Benzeval's signature image]

Professor Michaela Benzeval

Director, Understanding Society

Institute for Social and Economic Research

University of Essex

Appendix C – Recruitment Screener

Author: **Paul Vousden**

This questionnaire was written according to Kantar quality procedures

checked by **Alice Coulter**

B001 - B001: KANTAR PUBLIC QUAL - SCREENER

Begin block

B002 - B002: RESPONDENTDETAILS

Begin block

Q001 - RESPONDENTSDETAILS:

Open

FULL NAME

ADDRESS:

POSTCODE:

PRIMARY PHONE NUMBER

EMAIL ADDRESS:

PLEASE WRITE CLEARLY

Q002 - Recruitmentmethod:

Single coded

Normal

1 Client sample

Q003 - Recruitersdeclaration:**Open**

The person named above has been recruited by me in accordance with the instructions and within the Market Research Society Code of Conduct.

SIGNED**NAME****DATE****BACKCHECKED: YES / NO**

| |
|--|
| |
|--|

B002 - B002: RESPONDENTDETAILS**End block****Q004 - QUOTAS:****Open****RECRUIT 25 RESPONDENTS FOR 25 x 45 MINUTE INTERVIEWS****QUOTAS:**

| <i>Good spread across 3 locations: London, South East, South West, East Midlands, and Yorkshire & the Humber.</i> | | GENDER | |
|---|-------|---------------|-----------|
| | | Male | Female |
| AGE | 18-24 | 3 | 3 |
| | 25-34 | 3 | 3 |
| | 35-44 | 3 | 2 |
| | 45-54 | 2 | 2 |
| | 55+ | 2 | 2 |
| <i>Total interviews n=25</i> | | 13 | 12 |

Q005 - INTRODUCTION:

Single coded

Good morning / afternoon, my name is X and I'm calling from Kantar Public, an independent research organisation.

You will have recently received a letter about the upcoming research on the collection of biomesures (which can include blood, tissue and stool samples). The collection of these biomesures would help researchers understand influences on health and disease.

We have been asked by The Institute for Social and Economic Research / University of Essex to carry out research into people's thoughts and willingness to have certain biomesures collected.

The research would be in the form of a 45 minute in home discussion to talk about your thoughts on how these studies could be carried out. We will not be collecting any samples as part of the research.

The research is completely voluntary, confidential and anonymous.

Kantar Public is completely independent

Kantar Public will not be giving the ISER/University of Essex any details of respondents that could be traced back to them.

Taking part in this piece of research would in no way effect your relationship with ISER/University of Essex

We were wondering if you'd be interested in taking part?

- 1. Yes
- 2. No

IF CODE 2 = DO NOT RECRUIT

Normal

- 1 Yes
- 2 No

B003 - B004: DEMOGRAPHICS

Begin block

Q006 - GENDER:

Single coded

Note the gender of the respondent.

NOTE TO RECRUITER DO NOT ASK CHECK AGAINST SAMPLE RECRUIT TO QUOTA

Normal

- 1 Male
- 2 Female
- 3 Other - Specify.....
- 4 Prefer not to answer

Q007 - AGE:**Single coded**

What age were you on your last birthday?

NOTE TO RECRUITER DO NOT ASK CHECK AGAINST SAMPLE

IF CODE 1 = DO NOT RECRUIT
RECRUIT TO QUOTA**Normal**

- | | |
|---|----------|
| 1 | Under 18 |
| 2 | 18-24 |
| 3 | 25-34 |
| 4 | 35-44 |
| 5 | 45-54 |
| 6 | 55+ |

Q008 - CHECKQUESTION:**Text****Not back**

RECRUITER TO CHECK

- IF AT Q6 CODE = MALE AND AT Q7 CODE = 18-24 RECRUIT 3
 IF AT Q6 CODE = FEMALE AND AT Q7 CODE = 18-24 RECRUIT 3
 IF AT Q6 CODE = MALE AND AT Q7 CODE = 25-34 RECRUIT 3
 IF AT Q6 CODE = FEMALE AND AT Q7 CODE = 25-34 RECRUIT 3
 IF AT Q6 CODE = MALE AND AT Q7 CODE = 35-44 RECRUIT 3
 IF AT Q6 CODE = FEMALE AND AT Q7 CODE = 35-44 RECRUIT 2
 IF AT Q6 CODE = MALE AND AT Q7 CODE = 45-54 RECRUIT 2
 IF AT Q6 CODE = FEMALE AND AT Q7 CODE = 45-54 RECRUIT 2
 IF AT Q6 CODE = MALE AND AT Q7 CODE = 55+ RECRUIT 2
 IF AT Q6 CODE = FEMALE AND AT Q7 CODE = 55+ RECRUIT 2

Q009 - AREA:**Single coded****Not back**

In which area of the country do you live?

NOTE TO RECRUITER DO NOT ASK RECORD FROM SAMPLE
 AIM TO RECRUIT A SPREAD
 RECRUIT MIN 3 PER DAY OF FIELDWORK IN LONDON
 RECRUIT MIN OF 2 PER DAY OF FIELDWORK IN ALL OTHER AREAS
 WHERE POSSIBLE RECRUIT 4 PER DAY

Normal

- | | |
|---|------------------------|
| 1 | London |
| 2 | South East |
| 3 | East Midlands |
| 4 | Yorkshire & The Humber |

Q010 - ETHNICITY:

Single coded

How would you describe your ethnicity?

MONITOR

Normal

- 1 White - British
- 2 White - Irish
- 3 Any other white background
- 4 Mixed - White & Black Caribbean
- 5 Mixed - White & Black African
- 6 Mixed - White & Asian
- 7 Any other mixed background
- 8 Chinese or other Ethnic group - Chinese
- 9 Chinese or other Ethnic group - Any other
- 10 Black or Black British - Caribbean
- 11 Black or Black British - African
- 12 Any other Black background
- 13 Asian or Asian British - Indian
- 14 Asian or Asian British - Pakistani
- 15 Asian or Asian British - Bangladeshi
- 16 Any other Asian background
- 17 Refused

Q011 - SEG:

Single coded

What is/was the occupation of the chief income earner in your household?

PROBE FULLY, WRITE IN AND CODE BELOW:

.....

MONITOR

Normal

- 1 AB
- 2 C1C2
- 3 DE

B003 - B004: DEMOGRAPHICS

End block

B004 - B009: PRIVACYPOLICY

Begin block

B004 - B009: PRIVACYPOLICY

End block

Q012 - Q026:

Single coded

Not back

READ OUT: As part of our commitment to protecting your rights, please note that Kantar Public's privacy policy can be accessed on our website, uk.kantar.com/surveys. We can also provide you with a written copy of the policy.

RECRUITER, CONFIRM THAT PARTICIPANT HAS BEEN MADE AWARE OF HOW TO ACCESS PRIVACY POLICY. DO NOT RECRUIT OTHERWISE.

Normal

1 YES - PARTICIPANT HAS BEEN MADE AWARE OF PRIVACY POLICY

B005 - B008: GROUP DETAILS

Begin block

Q013 - T2:

Text

We would like to invite you to take part in a 45 minute face to face discussion about the collection of microbiomes, more specifically stool samples.

The discussion will take place:

Date: tbc

Time: tbc

Venue: in home

As a thank you for taking part we would like to offer you £40 as a PayPal transfer paid into an account of your choosing or £40 in online PERKS vouchers

RECRUITER TO READ OUT:The research is completely voluntary (you can stop participating at any time and participation will not affect your relationship with ISER/University of Essex. The research is anonymous. We will not share your name or details with the client. KANTAR PUBLIC is completely independent from ISER/University of Essex We will be audio/video recording the discussions. These will be shared only with the KANTAR PUBLIC research team and used for research purposes only.

You do not need to have any prior knowledge to take part in this group. We will not be testing people's knowledge, but simply asking for people's views and opinions.

Would you be interested in participating in this research?

If no, please record reason.....

Details of the Kantar Public Privacy Policy can be found here <https://uk.kantar.com/surveys>

B005 - B008: GROUP DETAILS

End block

B001 - B001: KANTAR PUBLIC QUAL - SCREENER

End block

Appendix D – Discussion Guide

ISER – Understanding Society Microbiome Pilot Interviews

Depth interview topic guide v1.0

Background and aims

Understanding Society is a UK Household Longitudinal Study that follows the lives of thousands of individuals within households over time. It is an internationally recognised study led by the Institute for Social and Economic Research (ISER) at the University of Essex. It provides vital evidence for scientists and policymakers on the causes and consequences of deep-rooted social problems.

The collection of stool samples for microbiome analysis ('gut bacteria') has the potential to provide a novel and useful biosocial insight. In the UK, older people (aged between 60 and 75 years in England, Wales and NI, from 50 in Scotland, and soon England) may have been invited to provide this sort of sample as part of the national bowel cancer screening programme. It is however, unclear how acceptable the collection of this sample would be to Understanding Society participants, who are across the entire age span.

No biological samples will be collected at any point during this pilot study.

This research study has the following aims:

- **Aim 1: Participants' feedback on acceptability on providing a stool sample**
ISER wish to determine participants' views and feedback on providing a stool sample for microbiome analysis. This is of importance to the Understanding Society longitudinal study to ensure that including a request to collect a stool sample from participants would not result in participant drop-outs and reduced uptake in future sample / data collection waves.
- **Aim 2: Development of study material**
ISER wish to get participant feedback on prospective documents and material that may be used for the study (from recruitment to sample collection protocols), to ensure all materials used are participant-friendly and provide the information participants would require in a clear and concise manner, to make an informed decision.

This research study will also involve asking participants to review commercially available stool collection kits.

Equipment list

- Dictaphone
- Participant Consent Form (for participation in this research)
- Different colour pens

Stimulus list

- **STIM A:** Advance Letter #1
- **STIM B:** Advance Letter #2
- **STIM C:** Participant Information Sheet
- **STIM D:** Information Postcard
- **STIM E:** Participant Consent Form
- **STIM F:** Stool Sample Collection Protocol
- **STIM G:** Stool Collection Kit #1
- **STIM H:** Stool Collection Kit #2
- **STIM I:** Stool Collection Kit #3
- **STIM J:** Stool Collection Kit #4

Please note, this guide is not a script and is intended to be used flexibly, with participant responses guiding the flow of the conversation, topics covered in the order that they naturally arise and probes used only when needed.

1. Introduction minutes)

(2



- **Warm up and introduction:**
 - Introduce moderator and Kantar Public
 - **Client:** Research on behalf of University of Essex
 - **Aim** of the discussion is to understand their views on acceptability of collection of biomeasures as part of the Understanding Society study and get feedback on written informational materials that would be used as part of the study
 - **Interview length** – up to 45 minutes
 - **Reassurances:** the interview is not a test and there are no right or wrong answers. We want honest feedback on the materials we'll be showing.
 - **Voluntary:** Research is voluntary and they have the right to withdraw at any time
 - **Confidentiality:** All information given will be kept confidential and will only be accessible by Kantar's research team. Kantar Public will not link participants' names with any information they give. Personal details and identifying information (such as name) will be removed from any outputs.
 - **Privacy Policy:** *Please note that Kantar Public's privacy policy can be accessed online, just search for 'Kantar Privacy Policy' or you can visit: uk.kantar.com/surveys*
 - **Participant Consent Form:** Hand participant consent form, allow them to read it and sign
 - **Audio recording:** check they are happy to be recorded. Audio files will be transcribed and anonymised for analysis.
 - **Turn on audio recorder** and confirm consent to audio record
 - Any questions?

2. Participant background (3 mins)

- **About them**
 - How they spend their time e.g. work, volunteering, looking after children
 - What they do for work (where relevant)
 - Who they live with
 - Family context e.g. whether married, whether have children (ages of children)
- **Understanding Society**
 - How long they've been involved in the Understanding Society study
 - Motivations for participating in Understanding Society
 - What they like about participating in Understanding Society

3. Advance letters, information sheets, consent form (20 mins)

Researcher to explain: You're going to show them two different letters to gather their views. After handing them each letter, explain that you would like them read it and mark up the letter highlighting words that stand out or anything that is unclear or they don't understand.

Researcher to hand participant STIM A or STIM B (researcher to rotate order during interviews)

For each letter, explore:

- Initial reactions

- Spontaneous
- What stood out
- How it makes them feel
- Ask them to describe in their own words what they're being asked to do
 - Anything confusing or unclear?
- What questions or concerns, if any, do they have – note (but do not probe) if any of these relate to:
 - Purpose (e.g. why this data is being requested)
 - Process (e.g. sample collection, storage, delivery)
 - Privacy (e.g. confidentiality, data security)
 - Other (e.g. embarrassment, hygiene, personal benefit, such as diagnostic information)
- For any questions raised, what do they anticipate the answers might be
- How they would respond to the request
 - Reasons for this
- Whether this is enough information to make a decision about whether to take part
 - What further information, if any, they would like – if necessary, prompt in relation to questions raised earlier

After both letters have been reviewed, explore briefly:

- How the letters compare
 - Views on shorter vs. longer letter
 - Less vs. more information
 - Any preferences?
- What changes they would make to either letter to make it **clearer** or **more appealing** e.g. language, content
 - Reasons for this

Researcher to explain: You're going to show them information that those who agree to take part in the study would receive. The aim is to gather their views on the information provided.

Hand participant Information Sheet and Post Card (STIM C and STIM D)

- **Information Sheet and Post Card**
 - Initial reactions (spontaneous)
 - What stood out
 - How it makes them feel
 - Anything confusing or unclear?
 - What questions, if any, do they have
- **When they would like to receive this**
 - When it would be most useful
 - Reasons for this

Researcher to explain: You're going to show them a consent form that those who agree to take part in the study would receive and sign to indicate their consent to take part.

Hand participant Consent Form (STIM E)

- **Explore understanding of consent form**
 - Initial reactions
 - Anything confusing or unclear?
 - What questions, if any, do they have

4. Collection Protocol and Kits (10 mins)

Researcher to explain: We're going to look at the instructions that would be sent to participants for collecting a stool sample and the different kits that could be used by participants to collect the sample.

Hand participant the Stool Sample Collection Protocol (STIM F) and STIM H and allow them time to read through it and look at the kit.

Once they've finished, explore:

- Initial reactions (spontaneous)
- What stood out
- How it makes them feel
- Anything confusing or unclear?
- What questions, if any, do they have
- What changes, if any, would they make?

Hand participant each remaining kit in turn (STIM G, I, J)

For each kit, explore briefly:

- Initial reactions (spontaneous)
- How it makes them feel
- Anything surprising?
- Anything confusing or unclear?
- What questions or concerns, if any, do they have

Explore whether any preferences amongst the collection kits

Researcher to explain: For Kit #1, 2, and 3 the stool sample would have to be stored in the freezer. In Kit #4 the tube has a liquid in it, which means once collected, the stool sample would not need to be kept in the freezer.

- **Explore views on this and whether that addresses any concerns raised about storage**

Researcher to explain: The collection could be done in a number of ways: either researcher administered, nurse administered, or self-administered:

- *Researcher/nurse administered: At the end of the interview, researcher/nurse would ask participant if they would be willing to participate in a biological sample collection and if they agree, a sample collection kit with instructions will be left behind with them.*
- *Self-administered: After completing the questionnaire online, at the end they would be asked if they were willing to participate in a biological sample collection. If participant agrees, a sample collection would be posted to their home.*

- **Explore preferences**
 - Which approach would they be most comfortable with?
 - Explore reasons for views
 - What questions, if any, do they have
 - What concerns, if any, would they have about each of the collection approaches

Researcher to explain: The sample could be returned in a number of ways: either picked up by a courier, collected by a nurse during their Understanding Society interview appointment, or they could post it themselves

- **Explore preferences for returning sample**
 - Whether they would prefer sample to be picked up by a courier or by a nurse during Understanding Society interview, or to post it themselves
 - Reasons for views
 - What questions, if any, do they have
 - What concerns, if any, would they have about each of the collection options

5. Overall reflections (10 mins)

- **Explore understanding of bio-measures and value of bio-measures data collection/analysis**
 - How they would explain to a family member the reason behind taking a stool sample
 - How far they accept the information provided in the information sheet (STIM C)
 - What questions, if any, do they have
- **Overall views on providing stool sample**
 - Whether they would agree to take part
 - If no, what, if anything, would reassure them
 - If yes, reasons for this
 - Do they have any outstanding questions or concerns?
 - How does a stool sample compare to providing hair / blood samples
 - How similar or different
 - Have they ever provided a stool sample before (e.g. for medical test); if so, how does this compare
 - Do they think others would agree to take part?
 - Why / why not
 - What might others be concerned about
 - What might encourage others to take part
- **Overall views on study materials**
 - Most important information to communicate
 - What information, if any, is missing
- **Any other final thoughts or reflections**

6. Close

- Reminder of incentive (£40) [Note: either PayPal, PERKS, or Love2Shop]

- Hand participant 'Hello from Kantar' leaflet
- Thanks and close

Appendix E – Advance Letter 1

Dear (Participant name),

We would like to invite you to participate in the *Understanding Society* Microbiome Pilot Study. This is a new project we are undertaking to better understand the different types of bacteria that live in the bowels of different people. In particular, we hope to learn how the different types of bacteria are influenced by differences in lifestyle and environment.

If you agree to take part, we would ask you to provide us with a stool sample and complete a short questionnaire about your general health, lifestyle and dietary habits. You will also need to provide informed consent. Collection of the stool sample and informed consent will be arranged by our fieldwork team.

Please contact us if there is anything that is not clear or if you would like more information about the study using the contact details at the end of this sheet.

If you're willing to be contacted by us, then you do not need to reply to this letter. If you would prefer not to participate (or be contacted), please contact us on (Freephone number) or by sending us an e-mail on (KP e-mail address) or completing the enclosed opt-out slip and returning it to the freepost address below.

Yours Sincerely,

xxxx

Study contact details for participants

Freephone number: xxxx

E-mail address: xxxx

Freepost address: xxxx

Appendix F – Advance Letter 2

Dear (Participant name),

We would like to invite you to participate in the Understanding Society Microbiome Pilot Study. This is a new project we are undertaking to better understand the different types of bacteria that live in the bowels of different people. In particular, we hope to learn how the different types of bacteria are influenced by differences in lifestyle and environment.

Why is this study being done?

Our bodies carry around trillions of microbes (such as bacteria and viruses) invisible to the naked eye. These microbes live on our skin and in places like our mouth, nose and gut. These groups of microbes that live on or inside our bodies can affect our health. Changes in our health can also affect these groups of microbes. The types of microbes that live on or inside us can also change by where we live or work, our age, health status and diet and possibly many other factors that we are currently not aware of.

People and microbes both have DNA – material that provides genetic instructions that affect how the microbes act in our bodies, how they live with each and how we react to them. All the different kinds of microbes that live on and inside us combined are called the “human microbiome”. In the microbiome pilot study we will only be examining the microbes’ DNA. Your DNA will not be analysed.

What would it involve?

If you agree to take part, we would ask you to provide us with a stool sample and complete a short questionnaire about your general health, lifestyle and dietary habits. This is a pilot study and we will not be asking you to provide a repeat sample for this study. You will also need to provide informed consent. Collection of the stool sample and informed consent will be arranged by our fieldwork team. They will provide you with a stool collection kit and details about collecting and transporting your stool sample. This is a very simple procedure that can be done from the comfort of your home. The whole process is very straightforward and should take you just a few minutes.

No clinical diagnostic tests will be performed on your stool sample, and you will not be informed of the results of any studies specifically relating to your sample. This means that we do not expect to find any directly clinically relevant incidental findings related to your health.

Please contact us if there is anything that is not clear or if you would like more information about the study using the contact details at the end of this sheet.

If you’re willing to be contacted by us, then you do not need to reply to this letter. If you would prefer not to participate (or be contacted), please contact us on (Freephone number) or by sending us an e-mail on (KP e-mail address) or completing the enclosed opt-out slip and returning it to the freepost address below.

Yours Sincerely,

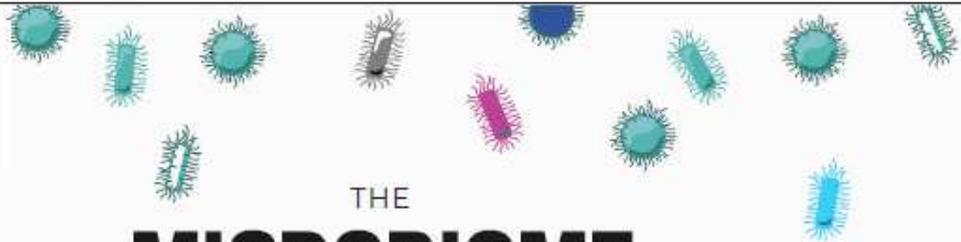
xxxx

Study contact details for participants

Freephone number: xxxx

E-mail address: xxxx

Freepost address: xxxx



THE
MICROBIOME
 PILOT STUDY
INFORMATION

WHY IS THE STUDY BEING DONE?

Our bodies carry around trillions of microbes, such as bacteria and viruses, that are invisible to the naked eye. These microbes live on our skin and in our mouth, nose and gut.



All the different kinds of microbes that live on and in us are called the "human microbiome"



Our gut microbes can be affected by



where we live and work



our age

our health



and our diet



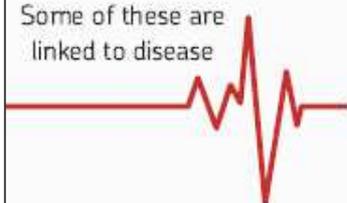
In the microbiome pilot study we will be examining the microbes living in your gut.

HOW DO MICROBES AFFECT YOUR BODY?

From childhood, as you grow, your gut microbiome begins to develop. By the time you are an adult you will have many different types of microbes.



Some of these are linked to disease



but others are extremely important and useful of your immune system, heart, weight and other aspects of health.

Recent research has shown that the microbes in our gut may play a role in

Alzheimer's disease

obesity

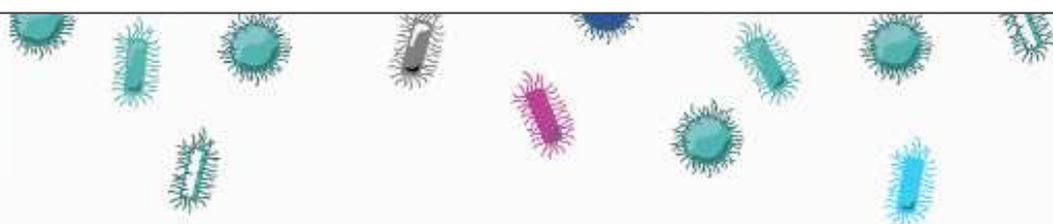
diabetes

heart health

depression

www.understandingsociety.ac.uk

Appendix G – Participant Information Sheet



"You may want to talk to friends or family about the study before you decide whether to take part."



You will need to give us informed consent before you take part.

WHAT WILL I HAVE TO DO?



If you agree to take part you would need to provide us with a stool sample and complete a short questionnaire about your health, lifestyle and diet.



Our fieldwork agency will contact you and give you a stool collection kit that you use at home. The kit attaches securely to your toilet and is simple and clean to use. The whole process of collecting your stool sample should take just a few minutes.



Once your sample is ready, it can be collected by a courier who will securely transport the sample to the laboratory for analysis. Or your sample can be collected by the nurse when she visits you for your Understanding Society interview.

Whichever collection method you choose your sample will need to be stored in your freezer until it can be collected.



Don't worry! The sample is securely packed and wrapped and is clean and hygienic.

WHAT WILL HAPPEN TO MY SAMPLE?



People and microbes both have DNA – the material that provides genetic instructions that affect how the microbes act in our bodies, how they live with each other and how we react to them. In this study we will analyse the DNA of the microbes in your stool sample. We will not be analysing your DNA.

Researchers will compare

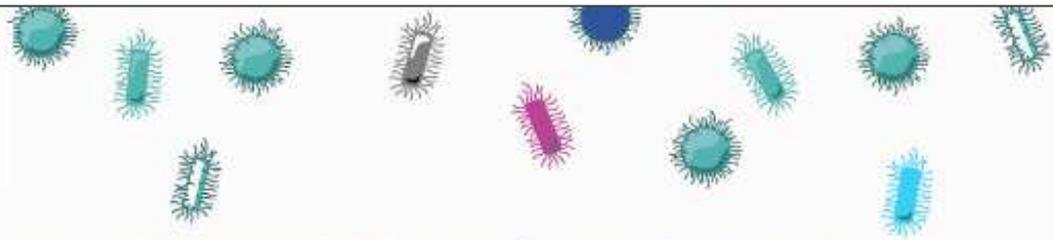
the DNA of the microbes in your sample



with the DNA of known microbes that have already been studied.

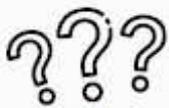
Your sample will be securely stored for the duration of the project. We'll ask for your consent to keep the sample for longer term research.





"Participating in this study is completely voluntary. You can take part in the main Understanding Society study and choose not to participate in the Microbiome Pilot study. You can withdraw from the Microbiome Pilot study at any time - you don't need to give us a reason."

CAN I RECEIVE RESULTS FROM MY SAMPLE?



No. We can't give you individual results from your sample.

This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately.



No clinical diagnostic tests will be performed on your stool sample. This means that we do not expect to find any directly clinically relevant incidental findings related to your health.



Your sample will only be used for research purposes.

ARE THERE ANY RISKS TO ME?



On a practical level, there is a very low risk of skin contamination with faeces during the collection process. Wearing the gloves provided in the collection kit will minimise this risk,



What about my information?

All personal information (such as name, sex, date of birth) will be removed from the samples and replaced with an anonymous number. Your information will be kept confidential and secure at all times.



If you have any questions please contact the study team.



telephone: 888888888



email: info@



postal address:
Understanding Society
University of Essex
Colchester, CO4 3SQ

The samples may be sent to specialist laboratories in the UK or abroad for analysis and the data sent back to Understanding Society. Researchers at these laboratories have no access to any personal information of study participants.



Appendix H – Consent Form

MICROBIOME PILOT STUDY CONSENT FORM

If you wish to give consent, please initial the box after each statement

| | Initial as appropriate |
|--|------------------------|
| 1. I consent to providing a stool sample of behalf of the Institute for Social and Economic Research | |
| 2. I have read and understood the Participant Information Sheet about the Microbiome Pilot Study. The nurse/interviewer has explained the procedures and risks, and I have had an opportunity to discuss these with him/her | |
| 3. I confirm that I have had the opportunity to ask questions and that these have been answered satisfactorily | |
| 4. I agree to my samples being stored securely and used for the Microbiome Pilot study | |
| 5. I understand that all personal identifiable information will be removed from the samples and data and replaced with an anonymised code. Data will be used for statistical analysis and not linked to any named participant. | |
| 6. I agree to my samples being stored and used for future research | |
| 7. I understand that my participation is voluntary and I can withdraw my consent at any time The consent process has been clearly explained to me and I understand how to withdraw my consent | |

Print name (Respondent):

Signed (Respondent):

Date:

Print name (Nurse/interviewer):

Signed (Nurse/interviewer):

Date:

Appendix I – Collection Protocol

STOOL SAMPLE COLLECTION PROTOCOL

We have included the following things in your sample collection pack which you will need to provide a sample.

- 1) Two pairs of gloves
- 2) A paper/cardboard disposable bowl (depending on the kit used)
- 3) Two tubes with an attached spoon
- 4) A small clear sealable plastic bag
- 5) A large clear sealable plastic bag
- 6) A sample collection record sheet
- 7) Anti-bacterial wipes
- 8) Yellow waste bag

Before collecting your sample please take note of these important points:

- Always wear gloves when collecting your sample
- Don't allow the sample to touch the inside of the toilet. If it does touch the toilet make a note of this in the sample collection record sheet.
- Avoid collecting urine or water (from the toilet) with the sample. If you need to urinate, please do so before collecting the sample
- Dispose of the cardboard bowl, gloves and used wipes into the yellow waste bag when you have finished and put it in the black bin .
- Wash your hands thoroughly when the sample collection is completed.

Collecting your sample

- 1) Take the stool collection kit to the toilet
- 2) Put on the gloves provided in the pack
- 3) Attach the paper collection device to the toilet-seat using the adhesive tape strips (this might vary depending on the type of kit used)

- 4) Produce a stool sample into the paper collection device (avoid urinating onto it)
- 5) Un-screw the cap of the collection tube and using the spoon place about two scoopfuls into the tube and close the lid tightly (with the spoon attached)
- 6) Repeat this with the second tube.
- 7) Flush the remaining stool down the toilet (if the paper collection disc is used this can be flushed down the toilet)
- 8) Place both tubes in the small plastic bag and wipe the outside with the antibacterial wipe.
- 9) Place the cardboard bowl (depending on which collection kit was used), used wipes and gloves into the yellow waste bag, tie it and place it your normal black bin.
- 10) Now wash your hands thoroughly.
- 11) Put the bag containing the sample and the form into your freezer until it is collected.
- 12) When your sample is ready, contact us using the details given below, and we will arrange to have your sample collected by a courier, who will securely transport the sample to the laboratory for analysis. If you would prefer, we could arrange to have your sample collected by the nurse when she visits you for your pre-arranged interview for the main *Understanding Society* study.

Study contact information

Freephone number: xxxx

E-mail address: xxxx

Freepost address: xxxx

Appendix J – Collection Kits

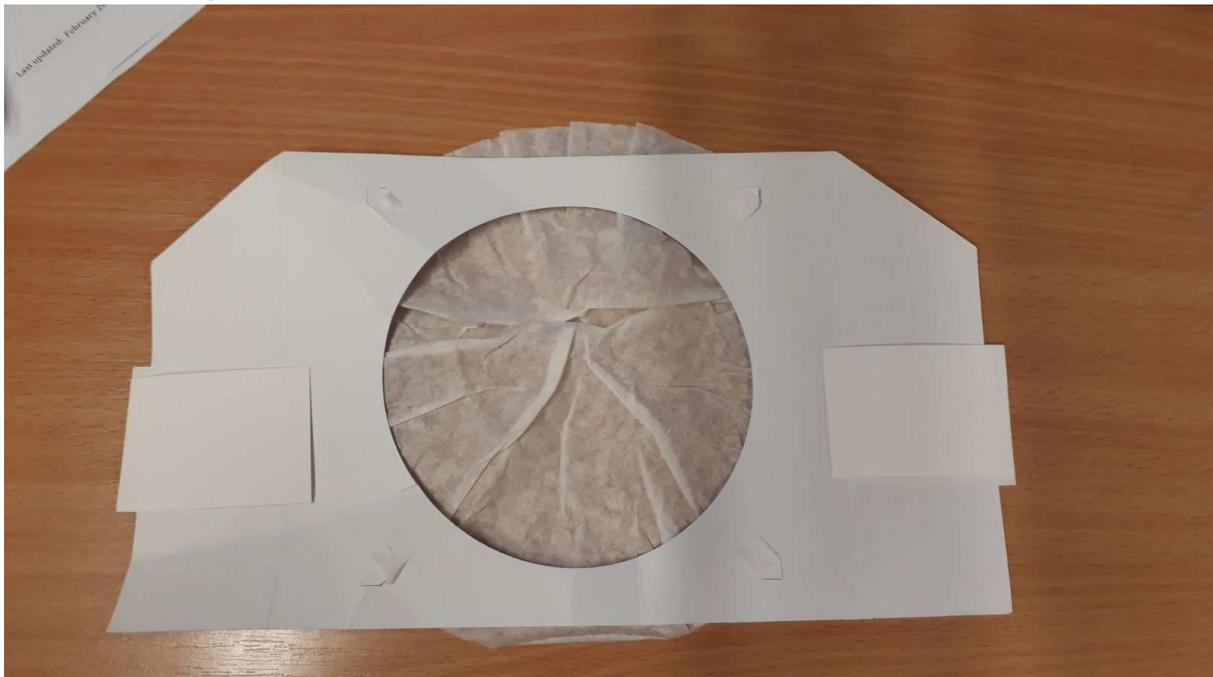
Stool collection kits that will be shown to participants

RESEACHER NOTE: Each interviewers will be given one of each of these kits and will be taking them to the interviews to get participant feedback.

1. Kit for collecting full stool sample (**STIM G**)



2. Kit for collecting partial stool samples (**STIM H**)



3. Kit for collecting partial stool samples (STIM I)



4. Kit for collecting partial stool samples (STIM J)

